



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0553]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Potential Tobacco Product Violations Reporting Form". Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Potential Tobacco Product Violations Reporting Form--(OMB Control Number 0910-NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321 et. seq.) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

FDA is requesting OMB approval for a new collection of information to accept consumer and other stakeholder feedback and notification of potential tobacco violations of the FD&C Act, as amended by the Tobacco Control Act.

As part of its enforcement strategy, FDA created a Tobacco Call Center (with a toll-free number: 1-877-CTP-1373) to accept information from the public about violations of the Tobacco Control Act. Callers are able to report potential violations of the Tobacco Control Act, and FDA may conduct targeted followup investigation based on information received. When callers report a violation, the caller will be asked to provide as much information as they can recall, including: The date the potential violation happened, the product type (e.g., cigarette, smokeless, roll-your-

own, etc.), tobacco brand, type of potentially violative promotional materials, potential violation type, who potentially violated, and the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation. FDA has developed a form that will be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Reporting), which is expected to eventually replace current Form FDA 3734 for Cigarette Flavor Ban Violations. This new form will be posted on FDA's Web site, and information may be submitted by filling out the form online (or the public can request a copy of Form FDA 3779 by contacting the Center for Tobacco Products (CTP)). In addition, FDA has developed a smartphone application for use with mobile devices (i.e., iPhones, Android) to allow consumers to report potential violations to FDA via their smartphone. Others may simply choose to send a letter to FDA with their information. In summary, the public and interested stakeholders will be able to report information regarding possible violations of the Tobacco Control Act through the following methods: Calling the Tobacco Call Center using CTP's toll-free number, using a fillable form found on FDA's Web site, using FDA's tobacco violation reporting smartphone application, and sending a letter to FDA's Center for Tobacco Products.

In the Federal Register of August 22, 2011 (76 FR 52333), FDA published a 60-day notice requesting public comment on this proposed collection of information. FDA received 24 comment submissions, which included over 60 comments embedded. The comments have been summarized into four PRA-related areas as follows.

(Comment 1) FDA received several comments that said the Tobacco Control Act does not include a provision directing FDA to request or accept information on potential tobacco

product violations from the public and other stakeholder groups. The comments stated that the public and other stakeholder groups have not been trained to inspect retail tobacco operations, have not been trained to recognize or report tobacco product violations, and are not able to verify what does or does not constitute compliance with the Tobacco Control Act. Commenters also stated that a retailer of tobacco products could be targeted by overzealous stakeholders and unfairly earmarked by FDA for future inspections.

(Response) FDA disagrees with this comment. The Tobacco Control Act amended the FD&C Act by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. This includes broad authority to enforce the provisions of the Tobacco Control Act.

FDA is requesting OMB approval for a new collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act (TCA). This collection of information falls under FDA's responsibilities to monitor compliance with and enforce the TCA.

In addition, the proposed tobacco violation form does not require respondents to verify compliance with or violations of the TCA. Instead, the submitted information will be one source of information to help FDA identify potential areas for further Agency inquiry.

(Comment 2) FDA received several comments that stated that the form is contrary to and may violate Executive Order 13563, "Improving Regulation and Regulatory Review," the intent of which is to eliminate unnecessary and wasteful government regulations.

(Response) FDA disagrees with this comment. Executive Order 13563 pertains to unnecessary and wasteful regulations. This form is not a regulation but an extension of the

means that the public and stakeholders have to voluntarily report potential tobacco violations and events to FDA. Current methods of reporting are FDA's toll-free hotline number (1-877-CTP-1373), email (AskCTP@fda.hhs.gov), and Form FDA 3734. This form is not an inspection reporting form but is another, perhaps easier, way for the public and stakeholders to report information to FDA. No information received from the form will be forwarded to inspectors unless the information is deemed credible by FDA.

(Comment 3) Several comments questioned the burden to complete the form and the methodology used to compute total responses expected through the use of this form. Commenters also stated that the form is overly broad and includes some categories of tobacco products currently not regulated by FDA under the Tobacco Control Act. Commenters also stated that the form was redundant in places, while one commenter liked the form and encouraged FDA to make the public aware that the form exists.

(Response) FDA generally agrees with these comments, except with regard to the redundancy of the form. The time to gather information and complete the form has been tested internally to take no longer than 10 minutes. However, due to the comments received, FDA is revising the burden estimate upward to indicate that the form or mobile application will take 15 minutes to complete.

With regard to the form being overly broad, the Potential Tobacco Product Violations Reporting Form has been revised to ensure that it only lists currently regulated tobacco products and possible violations under the TCA for those products. Most notably, the word "other" has been removed from some of the questions on the form to reduce confusion about which tobacco products are regulated by FDA. The layout of the form has also been adjusted to make it easier for the public to voluntarily submit information to FDA. The intent of the form is not to gather

establishment inspection information like that collected by Federal, State, or local inspectors of tobacco facilities but to offer another means of contacting FDA about tobacco-related events and potential violations, such as that offered by the 1-877-CTP-1373 toll-free hotline and the AskCTP@fda.hhs.gov email address. The use of the form is voluntary and is not designed to target specific establishments or deputize the public as inspectors for identifying specific violations of the TCA.

With regard to the comments addressing the methodology for computing the burden, FDA has based this estimate on information received from several flavored cigarette reports, reports currently received from FDA's toll-free hotline and email address, and FDA experience. If the number of actual reports received is either too high or low, FDA will either correct the collection via a revision of the information collection or during its next renewal submission to OMB. Upon receiving OMB approval for the form and the collection of information, FDA will place the form on its complaint Web site and will advertise its location to the public.

With regard to the redundancy of fields of information on the form, FDA has reviewed all aspects of the form and mobile application carefully and has eliminated any redundant fields on the form.

(Comment 4) Several comments indicated that they thought the form is being used by the public and stakeholders as an inspection report to police or target tobacco retailers and the public, and that stakeholders have not been thoroughly or extensively trained with the training provided to FDA's Federal, State, and local inspectors. In addition to the lack of training, commenters also wondered what type of corrective action would or could be taken against a person or entity who files a false or inaccurate report against a retailer.

(Response) FDA's intent in creating this form and mobile application is not to target retailers but to provide the public and stakeholders with another means to report tobacco-related events, concerns, or potential violations, much like the information that is currently collected using the existing Center for Tobacco Products toll-free hotline telephone number, email address, and Form FDA 3774. The Web-based, paper, and mobile application form may allow the Agency to become better informed about certain tobacco-related topics and will provide the public and other stakeholders with an easier and possibly more efficient way to submit potential violation and event information to FDA. Information received by FDA from this form will not be forwarded to an inspector unless FDA deems the information is credible and worth further investigation. The information provided by this form will also help FDA more efficiently use its inspection resources, based on credible information provided by the public and stakeholders on potential events.

With regard to the type of corrective action taken against persons falsifying information submitted on these forms, FDA will scrutinize each submission carefully. Only forms containing information which are determined to be worthy of further investigation will be submitted to investigators for further review. Because this form is voluntary, submission of the information by the public and stakeholders does not guarantee that an investigation against a retailer will be triggered, and FDA will work to ensure that no specific retailer or supplier is unfairly targeted.

To clarify that Form FDA 3779 is not an inspection report, FDA is amending the title of Form FDA 3779 to "Potential Tobacco Product Violations Reporting." FDA is making this change to reflect that the form is voluntary, that the form is intended to be a means for the public to submit information to FDA regarding possible violations of the laws that it enforces, and that a Form FDA 3779 submission is not, by itself, enough to warrant further FDA action.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹					
Activity and Form FDA 3779	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Average Burden per Response	Total Hours
Reporting potential violations of the FD&C Act, as amended by the Tobacco Control Act, by telephone, Internet or paper form, smartphone application or email	1,000	1	1,000	0.25	250

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that submitting the information (by phone, Internet form, paper form by mail, smartphone application, or email) will take 15 minutes per response. Since a similar type of reporting went into effect for the cigarette flavor ban, FDA has received several reports via the Internet or email. Based on the rate of reporting for the cigarette flavor ban, reports received from FDA's toll-free telephone number and email address, and FDA experience, FDA estimates the number of annual respondents to this collection of information will be 1,000, who will each submit 1 report by phone, Internet form, paper form, smartphone application, or email. Each report is expected to take 15 minutes to complete and submit, therefore, total burden hours for this collection of information is estimated to be 250 hours (1,000 responses x 0.25 hours per response). Because of the variety of products regulated by FDA under the authority of the FD&C Act, as amended by the Tobacco Control Act, FDA expects the rate of calls and reports received to remain constant over the next 3 years.

Dated: March 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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